



Monday Morning Practice Pearls #44

What happens if a patient signs an informed consent document with dates outside of the approved date range?

The approved date range for each protocol is shown on the signature page right above the PI and witness signatures.

If a patient is accidentally consented to the protocol after the approved date range has passed, the CC Health Information Management Department (HIMD) will take the following steps:

1. Notify the PI via email that an invalid consent was used so that they can re-consent the patient to the current consent
2. Update the health issues section of CRIS to “confirmed” for that protocol. The onset date will reflect the day the patient first signed the consent, which in these cases will be the date they signed the invalid consent.
3. Mark the original consent with a “Valid Consent Requested” stamp and the date that the email was sent. This will show that it has been identified as invalid and the PI has been contacted.
4. Scan the original consent, upload to CRIS, and file in the patient’s medical record

The PI or designee will need to:

1. Re-consent the patient using the valid protocol consent obtained from https://clinicalstudies.info.nih.gov/protocol_consents/search.html
2. Document the re-consenting process in CRIS
3. Send valid signed consent to HIMD

When the patient is re-consented using the valid protocol consent, HIMD will review, scan, and file the consent into the patient’s record. The invalid consent will also remain in the record.

REMINDERS

1. The approved date range may not change with an amendment so make sure that you are using the correct version of the consent document as well. Pull all consents from the website above.
2. If you notice that any of the dates on the first or last page of the posted informed consent document are incorrect, notify the [NCI IRB Administrative Office](#) and copy your Protocol specialist.